

Notice of Allowability

Application No.

10/657,752

Examiner

Humera N. Sheikh

Applicant(s)

ALBERT ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to paper filed 26 September 2007.
2. ☒ The allowed claim(s) is/are 1-6, 9-24, 27-42, 45-80 and 117.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

7. ☒ The Drawings filed 9/9/03 are accepted by the Examiner.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date 06/05/07
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date 9/25/07
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.


HUMERA N. SHEIKH
PRIMARY EXAMINER

DETAILED ACTION

Status of the Application

Receipt of the Supplemental Amendment filed 09/26/07, the Response after Non-Final Office Action and Applicant's Arguments filed 04/13/07 and the Information Disclosure Statement (IDS) filed 06/05/07 is acknowledged.

Claims 1-6, 9-24, 27-42, 45-80 and 117 are pending in this action. Claims 1, 2, 19-24, 27-42, 45-54, 58, 60-70, 72-74, 78, 80 and 117 have been amended. New claim 117 has been added. Claims 7, 8, 25, 26, 43, 44 and 81-116 have been cancelled herein.

Allowable Subject Matter

Claims 1-6, 9-24, 27-42, 45-80 and 117 are allowed.

The following is an examiner's statement of reasons for allowance:

The primary reasons for allowance are that the prior art does not disclose nor fairly suggest or teach a method of treating myocardial ischemia in a patient that comprises the instant galenical preparation of diltiazem, contained in an amount of from about 180 mg to about 420 mg, administered every 24 hours to provide controlled release to achieve C_{\max} of diltiazem in the blood between about 10 and about 17 hours after administration. The prior art further fails to disclose or teach a controlled release galenical preparation of diltiazem having the instantly claimed dissolution profile of diltiazem over a 24-hour duration. There is no suggestion or

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teaching of the prior art to provide for a method of treating myocardial ischemia having the instant rates of release of active ingredient (diltiazem), nor the C_{\max} claimed in the instant diltiazem administration amounts during a 24-hour period.

In a telephonic interview held on 09/25/07 between Applicant's representative (Richard L. Treanor) and the Examiner of record (H. Sheikh), proposed suggestions were made by the Examiner, which would place the application in condition for allowance. The Examiner proposed the following: (1) To cancel the term "angina" from all pending claims; (2) To cancel claims directed to a) tablet alone and b) capsule alone, as these claims were directed to non-elected subject matter. (Applicant elected species drawn to "microcapsules"; see response to restriction filed 11/01/06). Examiner also agreed to examine/allow claims drawn to 'microcapsules in a tablet' and 'microcapsules in a capsule' (which correspond to withdrawn claims 71-73, 75, 76 & 79), in addition to the elected "microcapsules", as the prior art search was extended to include microcapsules in tablet & capsule form. Applicant's representative agreed to and accepted the proposed amendments made by the Examiner. Hence, the instant invention is rendered non-obvious and *patentable* over the cited art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday during regular business hours. (Wednesdays - Telework).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Humera N. Sheikh
Primary Examiner


HUMERA N SHEIKH
PRIMARY EXAMINER

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September 26, 2007

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